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|-----------------|-------------|----------------------|---------------------|------------------|
| 08/928,272      | 09/12/1997  | MICHAEL J. ISKRA     | P-3818              | 9434             |

7590 11/17/2009  
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| EXAMINER |
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MATTER, KRISTEN CLARETTE

|          |              |
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| ART UNIT | PAPER NUMBER |
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3771

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11/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>08/928,272 | <b>Applicant(s)</b><br>ISKRA, MICHAEL J. |  |
|                              | <b>Examiner</b><br>KRISTEN C. MATTER | <b>Art Unit</b><br>3771                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

This Action is in response to the Request for Continued Examination filed on 10/15/09. Claim 1 was amended and no claims were added or cancelled. Therefore, claims 1 and 5-9 are currently pending in the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1 and 5- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (US 5,458,854) in view of Arlman (US 3,918,909).**

Regarding claim 1, Burns discloses a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (see Figure 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (see Figure 2), said housing defining a volume for specimen collection and containment therein between said first end and said partition (see abstract), said second end forming a false bottom comprising a bottom end below said partition comprising an annular skirt (37) comprising an opening (47) therein.

The sole difference between Burns and the instant invention is the bottom of the tube being semi-spherical. However, absent a critical teaching and/or a showing of unexpected results from the tube having a semi-spherical bottom examiner contends that such a modification is an

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obvious design consideration to one of ordinary skill in the art as a mere change in shape that does not patentably distinguish an invention over the prior art. Changing the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube. In addition, Arlman teaches a specimen collection tube with a false bottom surface having a semi-spherical shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Burns device with a semi-spherical false bottom as taught by Arlman depending on the intended use of the device or to allow compatibility with standard clinical equipment because such a shape was well known at the time of the invention. Such a modification would involve substitution of a well known method (semi-spherical bottom) into a well known device to yield predictable results that do not patentably distinguish an invention over

Regarding claim 5, the partition disclosed by Burns is arcuate in shape and has at least a partially rounded bottom portion (see Figure 2).

Regarding claim 6, Burns lacks the partition being conical. However, absent a critical teaching and/or a showing of unexpected results from the partition being conical (as opposed to arcuate), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. Furthermore, it appears as though the tube of Burns would work equally well with any shape of partition so long as specimen could be retained.

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Regarding claims 7 and 8, Burns discloses the housing can be made of a thermoplastic polymer such as polyvinyl chloride (column 5, lines 43-50).

Regarding claim 9, Burns is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the Burns container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the device of Burns would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 and 5-9 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771